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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION, **Plaintiff,** **v.** **ONCOGEN PHARMA (MALAYSIA) SDN. BHD.,** **Defendant.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff Celgene Corporation ("Celgene"), by its undersigned attorneys, for its Complaint against Defendant Oncogen Pharma (Malaysia) Sdn. Bhd. ("Oncogen"), alleges as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq*., arising from Oncogen's submission of Abbreviated New Drug Application ("ANDA") No. 217281 ("Oncogen's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to manufacture, use, import, distribute, offer to sell, and/or sell generic versions of Celgene's Revlimid® drug products prior to the expiration of United States Patent Nos. 7,465,800 (the "'800 patent"), 7,855,217 (the "'217 patent"),

7,968,569 (the "'569 patent"), 8,530,498 (the "'498 patent"), 8,648,095 (the "'095 patent"), 9,101,621 (the "'621 patent"), and 9,101,622 (the "'622 patent") (collectively, "the patents-in-suit"), each owned by Celgene.

The Parties

2. Plaintiff Celgene is a biopharmaceutical company committed to improving the lives of patients worldwide. Celgene focuses on, and invests heavily in, the discovery and development of products for the treatment of severe and life-threatening conditions. Celgene is a world leader in the treatment of many such diseases, including cancer. Celgene is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

3. On information and belief, Defendant Oncogen is a corporation organized and existing under the laws of Malaysia, having a principal place of business at 3, Jalan Jururancang U1/21, Hicom-glenmarie Industrial Park, 40150 Shah Alam, Selangor, Malaysia.

The Patents-in-Suit

4. On December 16, 2008, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '800 patent, entitled, "Polymorphic Forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione." A copy of the '800 patent is attached hereto as Exhibit A.

5. On December 21, 2010, the USPTO duly and lawfully issued the '217 patent, entitled, "Polymorphic Forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione." A copy of the '217 patent is attached hereto as Exhibit B.

6. On June 28, 2011, the USPTO duly and lawfully issued the '569 patent, entitled, "Methods For Treatment of Multiple Myeloma Using 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione." A copy of the '569 patent is attached hereto as Exhibit C.

7. On September 10, 2013, the USPTO duly and lawfully issued the '498 patent, entitled, "Methods For Treating Multiple Myeloma With 3-(4-amino-1-oxo-1,3-dihydroisoindol-2-yl)piperidine-2,6-dione." A copy of the '498 patent is attached hereto as Exhibit D.

8. On February 11, 2014, the USPTO duly and lawfully issued the '095 patent, entitled, "Methods For Treating Multiple Myeloma Using 3-(4-amino-1-oxo-1,3-dihydroisoindol-2-yl)-piperidine-2,6-dione In Combination With Proteasome Inhibitor." A copy of the '095 patent is attached hereto as Exhibit E.

9. On August 11, 2015, the USPTO duly and lawfully issued the '621 patent, entitled, "Methods For Treating Multiple Myeloma With 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione After Stem Cell Transplantation." A copy of the '621 patent is attached hereto as Exhibit F.

10. On August 11, 2015, the USPTO duly and lawfully issued the '622 patent, entitled, "Methods For Treating Newly Diagnosed Multiple Myeloma 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione In Combination With Dexamethasone." A copy of the '622 patent is attached hereto as Exhibit G.

The Revlimid® Drug Product

11. Celgene holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for lenalidomide capsules (NDA No. 021880), which it sells under the trade name Revlimid®. The claims of the patents-in-suit cover, *inter alia*, solid forms of lenalidomide, pharmaceutical compositions

containing lenalidomide, and methods of use and administration of lenalidomide or pharmaceutical compositions containing lenalidomide.

12. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Revlimid®.

13. The labeling for Revlimid® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Revlimid® for the treatment of, *inter alia*, adult patients with multiple myeloma (MM), in combination with dexamethasone.

14. The labeling for Revlimid® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Revlimid® for the treatment of, *inter alia*, adult patients with MM, as maintenance following autologous hematopoietic stem cell transplantation (auto-HSCT).

15. The labeling for Revlimid® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Revlimid® according to one or more of the methods claimed in the patents-in-suit.

Jurisdiction and Venue

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

17. This Court has personal jurisdiction over Oncogen by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

18. On information and belief, Oncogen is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District,

through its own actions and/or through the actions of its agents, alter egos, and/or subsidiaries. On information and belief, Oncogen has purposefully conducted and continues to conduct business in this Judicial District. On information and belief, this Judicial District is a likely destination for the generic drug products described in Oncogen's ANDA.

19. On information and belief, Oncogen also prepares and/or aids in the preparation and submission of ANDAs to the FDA, including Oncogen's ANDA.

20. This Court has personal jurisdiction over Oncogen because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in New Jersey, including directly or indirectly through one or more agents and/or alter egos; and (2) maintains extensive and systematic contacts with the State of New Jersey, including through the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey, including through, directly or indirectly, one or more agents and/or alter egos.

21. On information and belief, Oncogen derives substantial revenue from directly or indirectly selling generic pharmaceutical products throughout the United States, including in this Judicial District.

22. In the alternative, this Court has personal jurisdiction over Oncogen because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Celgene's claims arise under federal law; (b) Oncogen is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Oncogen has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Oncogen satisfies due process.

23. On information and belief, Oncogen works in privity and/or concert either directly or indirectly through one or more of its agents, alter egos, and/or other related entities with respect to the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District.

24. On information and belief, Oncogen submitted and/or actively participated in the submission of Oncogen's ANDA. On information and belief, Oncogen will work in privity and/or concert with one or more agents, alter egos, and/or other related entities towards the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products, including Oncogen's Proposed Products, throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the patents-in-suit.

25. On information and belief, Oncogen intends to benefit directly if Oncogen's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug products that are the subject of Oncogen's ANDA.

26. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and/or 1400(b).

27. Venue is proper in this Judicial District for Oncogen pursuant to 28 U.S.C. §§ 1391 and/or 1400(b) because, *inter alia*, Oncogen is a company organized and existing under the laws of Malaysia and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

Acts Giving Rise To This Suit

28. Pursuant to Section 505 of the FFDCA, Oncogen submitted Oncogen's ANDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or

importation into the United States of 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg lenalidomide capsules ("Oncogen's Proposed Products"), before the patents-in-suit expire.

29. On information and belief, following FDA approval of Oncogen's ANDA, Oncogen will make, use, sell, or offer to sell Oncogen's Proposed Products throughout the United States, or import such generic products into the United States.

30. On information and belief, in connection with the submission of Oncogen's ANDA as described above, Oncogen provided a written certification to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Oncogen's Paragraph IV Certification"), alleging that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in Oncogen's ANDA.

31. No earlier than May 9, 2022, Oncogen sent a written notice of its Paragraph IV Certification to Celgene ("Oncogen's Notice Letter"). Oncogen's Notice Letter alleged that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in Oncogen's ANDA. Oncogen's Notice Letter also informed Celgene that Oncogen seeks approval to market Oncogen's Proposed Products before the patents-in-suit expire. Oncogen specifically directed Oncogen's Notice Letter to Celgene's headquarters in Summit, New Jersey, in this Judicial District.

Count I: Infringement of the '800 Patent

32. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

33. Oncogen's submission of Oncogen's ANDA, with the accompanying Paragraph IV Certification and notice to Celgene of same, to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Oncogen's Proposed Products, prior

to the expiration of the '800 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

34. There is a justiciable controversy between the parties hereto as to the infringement of the '800 patent.

35. Unless enjoined by this Court, upon FDA approval of Oncogen's ANDA, Oncogen will infringe one or more claims of the '800 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Oncogen's Proposed Products in the United States.

36. Unless enjoined by this Court, upon FDA approval of Oncogen's ANDA, Oncogen will induce infringement of one or more claims of the '800 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Oncogen's Proposed Products in the United States. On information and belief, upon FDA approval of Oncogen's ANDA, Oncogen will intentionally encourage acts of direct infringement with knowledge of the '800 patent and knowledge that its acts are encouraging infringement.

37. Unless enjoined by this Court, upon FDA approval of Oncogen's ANDA, Oncogen will contributorily infringe one or more claims of the '800 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Oncogen's Proposed Products in the United States. On information and belief, Oncogen has had and continues to have knowledge that Oncogen's Proposed Products are especially adapted for a use that infringes one or more claims of the '800 patent and that there is no substantial non-infringing use for Oncogen's Proposed Products.

38. Celgene will be substantially and irreparably damaged and harmed if Oncogen's infringement of the '800 patent is not enjoined.

39. Celgene does not have an adequate remedy at law.

40. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count II: Infringement of the '217 Patent

41. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

42. Oncogen's submission of Oncogen's ANDA, with the accompanying Paragraph IV Certification and notice to Celgene of same, to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Oncogen's Proposed Products, prior to the expiration of the '217 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

43. There is a justiciable controversy between the parties hereto as to the infringement of the '217 patent.

44. Unless enjoined by this Court, upon FDA approval of Oncogen's ANDA, Oncogen will infringe one or more claims of the '217 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Oncogen's Proposed Products in the United States.

45. Unless enjoined by this Court, upon FDA approval of Oncogen's ANDA, Oncogen will induce infringement of one or more claims of the '217 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Oncogen's Proposed Products in the United States. On information and belief, upon FDA approval of Oncogen's ANDA, Oncogen will intentionally encourage acts of direct infringement with knowledge of the '217 patent and knowledge that its acts are encouraging infringement.

46. Unless enjoined by this Court, upon FDA approval of Oncogen's ANDA, Oncogen will contributorily infringe one or more claims of the '217 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Oncogen's Proposed Products in the United States. On information and belief, Oncogen has had and continues to have knowledge that Oncogen's Proposed Products are especially adapted for a use that infringes one or more claims of the '217 patent and that there is no substantial non-infringing use for Oncogen's Proposed Products.

47. Celgene will be substantially and irreparably damaged and harmed if Oncogen's infringement of the '217 patent is not enjoined.

48. Celgene does not have an adequate remedy at law.

49. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count III: Infringement of the '569 Patent

50. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

51. Oncogen's submission of Oncogen's ANDA, with the accompanying Paragraph IV Certification and notice to Celgene of same, to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Oncogen's Proposed Products, prior to the expiration of the '569 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

52. There is a justiciable controversy between the parties hereto as to the infringement of the '569 patent.

53. Unless enjoined by this Court, upon FDA approval of Oncogen's ANDA, Oncogen will infringe one or more claims of the '569 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Oncogen's Proposed Products in the United States.

54. Unless enjoined by this Court, upon FDA approval of Oncogen's ANDA, Oncogen will induce infringement of one or more claims of the '569 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Oncogen's Proposed Products in the United States. On information and belief, upon FDA approval of Oncogen's ANDA, Oncogen will intentionally encourage acts of direct infringement with knowledge of the '569 patent and knowledge that its acts are encouraging infringement.

55. Unless enjoined by this Court, upon FDA approval of Oncogen's ANDA, Oncogen will contributorily infringe one or more claims of the '569 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Oncogen's Proposed Products in the United States. On information and belief, Oncogen has had and continues to have knowledge that Oncogen's Proposed Products are especially adapted for a use that infringes one or more claims of the '569 patent and that there is no substantial non-infringing use for Oncogen's Proposed Products.

56. Celgene will be substantially and irreparably damaged and harmed if Oncogen's infringement of the '569 patent is not enjoined.

57. Celgene does not have an adequate remedy at law.

58. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count IV: Infringement of the '498 Patent

59. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

60. Oncogen's submission of Oncogen's ANDA, with the accompanying Paragraph IV Certification and notice to Celgene of same, to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Oncogen's Proposed Products, prior to the expiration of the '498 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

61. There is a justiciable controversy between the parties hereto as to the infringement of the '498 patent.

62. Unless enjoined by this Court, upon FDA approval of Oncogen's ANDA, Oncogen will infringe one or more claims of the '498 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Oncogen's Proposed Products in the United States.

63. Unless enjoined by this Court, upon FDA approval of Oncogen's ANDA, Oncogen will induce infringement of one or more claims of the '498 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Oncogen's Proposed Products in the United States. On information and belief, upon FDA approval of Oncogen's ANDA, Oncogen will intentionally encourage acts of direct infringement with knowledge of the '498 patent and knowledge that its acts are encouraging infringement.

64. Unless enjoined by this Court, upon FDA approval of Oncogen's ANDA, Oncogen will contributorily infringe one or more claims of the '498 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Oncogen's Proposed

Products in the United States. On information and belief, Oncogen has had and continues to have knowledge that Oncogen's Proposed Products are especially adapted for a use that infringes one or more claims of the '498 patent and that there is no substantial non-infringing use for Oncogen's Proposed Products.

65. Celgene will be substantially and irreparably damaged and harmed if Oncogen's infringement of the '498 patent is not enjoined.

66. Celgene does not have an adequate remedy at law.

67. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count V: Infringement of the '095 Patent

68. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

69. Oncogen's submission of Oncogen's ANDA, with the accompanying Paragraph IV Certification and notice to Celgene of same, to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Oncogen's Proposed Products, prior to the expiration of the '095 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

70. There is a justiciable controversy between the parties hereto as to the infringement of the '095 patent.

71. Unless enjoined by this Court, upon FDA approval of Oncogen's ANDA, Oncogen will infringe one or more claims of the '095 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Oncogen's Proposed Products in the United States.

72. Unless enjoined by this Court, upon FDA approval of Oncogen's ANDA, Oncogen will induce infringement of one or more claims of the '095 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Oncogen's Proposed Products in the United States. On information and belief, upon FDA approval of Oncogen's ANDA, Oncogen will intentionally encourage acts of direct infringement with knowledge of the '095 patent and knowledge that its acts are encouraging infringement.

73. Unless enjoined by this Court, upon FDA approval of Oncogen's ANDA, Oncogen will contributorily infringe one or more claims of the '095 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Oncogen's Proposed Products in the United States. On information and belief, Oncogen has had and continues to have knowledge that Oncogen's Proposed Products are especially adapted for a use that infringes one or more claims of the '095 patent and that there is no substantial non-infringing use for Oncogen's Proposed Products.

74. Celgene will be substantially and irreparably damaged and harmed if Oncogen's infringement of the '095 patent is not enjoined.

75. Celgene does not have an adequate remedy at law.

76. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VI: Infringement of the '621 Patent

77. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

78. Oncogen's submission of Oncogen's ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Oncogen's

Proposed Products, prior to the expiration of the '621 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

79. There is a justiciable controversy between the parties hereto as to the infringement of the '621 patent.

80. Unless enjoined by this Court, upon FDA approval of Oncogen's ANDA, Oncogen will infringe one or more claims of the '621 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Oncogen's Proposed Products in the United States.

81. Unless enjoined by this Court, upon FDA approval of Oncogen's ANDA, Oncogen will induce infringement of one or more claims of the '621 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Oncogen's Proposed Products in the United States. On information and belief, upon FDA approval of Oncogen's ANDA, Oncogen will intentionally encourage acts of direct infringement with knowledge of the '621 patent and knowledge that its acts are encouraging infringement.

82. Unless enjoined by this Court, upon FDA approval of Oncogen's ANDA, Oncogen will contributorily infringe one or more claims of the '621 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Oncogen's Proposed Products in the United States. On information and belief, Oncogen has had and continues to have knowledge that Oncogen's Proposed Products are especially adapted for a use that infringes one or more claims of the '621 patent and that there is no substantial non-infringing use for Oncogen's Proposed Products.

83. Celgene will be substantially and irreparably damaged and harmed if Oncogen's infringement of the '621 patent is not enjoined.

84. Celgene does not have an adequate remedy at law.

85. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VII: Infringement of the '622 Patent

86. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

87. Oncogen's submission of Oncogen's ANDA, with the accompanying Paragraph IV Certification and notice to Celgene of same, to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Oncogen's Proposed Products, prior to the expiration of the '622 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

88. There is a justiciable controversy between the parties hereto as to the infringement of the '622 patent.

89. Unless enjoined by this Court, upon FDA approval of Oncogen's ANDA, Oncogen will infringe one or more claims of the '622 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Oncogen's Proposed Products in the United States.

90. Unless enjoined by this Court, upon FDA approval of Oncogen's ANDA, Oncogen will induce infringement of one or more claims of the '622 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Oncogen's Proposed Products in the United States. On information and belief, upon FDA approval of Oncogen's ANDA, Oncogen will intentionally encourage acts of direct infringement with knowledge of the '622 patent and knowledge that its acts are encouraging infringement.

91. Unless enjoined by this Court, upon FDA approval of Oncogen's ANDA, Oncogen will contributorily infringe one or more claims of the '622 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Oncogen's Proposed Products in the United States. On information and belief, Oncogen has had and continues to have knowledge that Oncogen's Proposed Products are especially adapted for a use that infringes one or more claims of the '622 patent and that there is no substantial non-infringing use for Oncogen's Proposed Products.

92. Celgene will be substantially and irreparably damaged and harmed if Oncogen's infringement of the '622 patent is not enjoined.

93. Celgene does not have an adequate remedy at law.

94. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Celgene respectfully requests the following relief:

(A) A Judgment that Oncogen has infringed the patents-in-suit by submitting ANDA No. 217281 with the accompanying Paragraph IV Certification and notice to Celgene of same;

(B) A Judgment that Oncogen has infringed, and that Oncogen's making, using, selling, offering to sell, or importing Oncogen's Proposed Products will infringe one or more claims of the patents-in-suit;

(C) An Order that the effective date of FDA approval of ANDA No. 217281 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Oncogen and its officers, agents, attorneys and employees, and those acting in privity and/or concert with them, from making, using, offering to sell, selling, or importing Oncogen's Proposed Products until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Oncogen, its officers, agents, attorneys and employees, and those acting in privity and/or concert with them, from practicing any solid forms of lenalidomide, compositions, or methods claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Oncogen's Proposed Products will directly infringe, induce infringement of, and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Oncogen, its officers, agents, attorneys and/or employees, or those acting in privity and/or concert with them, has committed any acts with respect to the solid forms of lenalidomide, compositions, or methods claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Celgene damages for such acts;

(H) If Oncogen, its officers, agents, attorneys and/or employees, or those acting in privity and/or concert with them, engages in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Oncogen's Proposed Products prior to the

expiration of the patents-in-suit, a Judgment awarding damages to Celgene resulting from such infringement, together with interest;

(I) A Judgment declaring that the patents-in-suit remain valid and enforceable;

(J) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Celgene its attorneys' fees incurred in this action;

(K) A Judgment awarding Celgene its costs and expenses incurred in this action; and

(L) Such further and other relief as this Court may deem just and proper.

Dated: May 20, 2022

By: s/ Charles M. Lizza

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the matter captioned *Celgene Corporation v. Alembic Pharmaceuticals Ltd.*, Civil Action 21-20099 (SDW)(LDW) (D.N.J.) is related to the matter in controversy because the matter in controversy involves the same plaintiff and the same patents, and because Oncogen is seeking FDA approval to market generic versions of the same pharmaceutical product.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: May 20, 2022

By: s/ Charles M. Lizza

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